REMARKS

Claims 88-101 are currently pending in the subject application. Applicant has hereinabove added new claims 102-105. Support for new claims 102 to 105 can be found in the specification as originally filed at page 5, lines 19-26; and page 7, lines 16 to 19. Applicant maintains that the amendments to the claims raise no issue of new matter. Accordingly, applicant respectfully requests entry of this Amendment.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 88-101 under 35 U.S.C. §103(a) as allegedly obvious over Metcalf et al. (of record) in view of ANAVAR® (of record) and Babu et al. (U.S. Patent No. 5,073,380). Specifically, the Examiner alleged that Metcalf teaches a method of using oxandrolone for nitrogen retention wherein the daily amounts of oxandrolone are from 5 mg, 10 mg, 20 mg, and up to 150 mg. The Examiner also alleged that oxandrolone was taken as a single dose daily, referring to page 60 of Metcalf, and that Metcalf teaches that the optimal dosage is 25 mg or 30 mg a day. The Examiner further asserted that Metcalf et al. expressly teach a dosage form comprising 10mg of oxandrolone and particular pharmaceutical excipients. The Examiner also asserted that ANAVAR® discloses an oxandrolone tablet, and discloses that the daily dosage of oxandrolone may be up to 20mg/day. The Examiner further asserted that Babu et al. disclose that hydroxypropyl methylcellulose is a typical excipient for tablet formulation. The Examiner alleged that it would have been prima facie obvious to one of ordinary skill in the art to make a dosage composition comprising 10mg oxandrolone with particular excipients, and that 10mg would have been obvious in view of the "the fact that it [would] have been used in the amount of 10mg, 20mg, and up to

150mg." The Examiner stated that "making a tablet with 10mg of oxandrolone for those use more than 10mg a time."

In response, applicant respectfully traverses the Examiner's rejection.

No Selection

Applicant maintains that the genus of ranges disclosed in Metcalf does not teach selection of the species recited in applicant's claim, i.e. of 10 mg. In regard to this, applicants note that the Examiner's assertion on page 1 of the March 26, 2007 Final Office Action that Metcalf "teaches expressly a dosage forms comprising 10mg of oxandrolone" is incorrect. Nowhere in Metcalf is such a unit dosage form taught.

Applicant notes that "the mere fact that a prior art genus contains a small number of members does not create a per se rule of obviousness. Some motivation to select the claimed species or subgenus must be taught by the prior art. See, e.g., Deuel, 51 F.3d at 1558-59, 34 USPQ2d at 1215", (MPEP §2144.08 (II)(A)(4)(a)). Moreover, "lack of any known useful properties weighs against a finding of motivation to make or select a species or subgenus. In re Albrecht, 514 F.2d 1389, 1392, 1395-96, 185 USPQ 585, 587, 590 (CCPA 1975)", (MPEP §2144.08 (II)(A)(4)(d)). Applicant maintains that Metcalf fails to teach or suggest a unit dose of 10 mg of oxandrolone. Accordingly, there is no suggestion by Metcalf, or in the art, to select the species of a 10mg dose form. Moreover, the apparent lack of such a dosage form being manufactured since Metcalf's 1965 publication (discussed hereinbelow under "secondary Considerations") is further argument that selection of this particular species is not obvious.

Metcalf Teaches Away From the Claimed Invention

Applicant maintains that Metcalf teaches away from the claimed invention because it discloses that the nitrogen retention for patients taking oxandrolone is at best ambiguous and, actually teaches that it is less effective in patients taking the presently claimed dosages.

As known in the art, nitrogen retention is a measure of therapeutic success in patients suffering from muscle wasting, myopathy, and low body weight from chronic human immunodeficiency virus type-1 infection. Thus, while the Examiner correctly points out that *Metcalf* discloses *total daily combined* oxandrolone amounts from 5, 10, 20 and up to 150 milligrams per day (Office Action at 2), Metcalf expressly acknowledges that the effects of such dosages were completely not understood. See, e.g. page 60 of Metcalf which states that the researchers were "uncertain which of the dose responses to include in the final analysis because of the variable response at low dose levels."

Accordingly, rather than suggesting applicant's claimed 10 mg solid dosage form, Metcalf actually teaches away from the claimed invention by clearly teaching that amounts less than the "optimum" dosage levels of 25 milligrams did not help patients retain nitrogen. Clearly, Metcalf's teaching would lead one away from a 10mg dosage form.

No Reasonable Expectation of Success

Metcalf explicitly teaches that the optimal combined daily amount is 25-30mg per day (see Metcalf, p63) and discuss the "variable response at low dose levels" (see Metcalf, p60). Applicant maintains that a one of ordinary skill in the art would not be motivated to produce a 10mg unit dosage form based on Metcalf's express teaching that such a low dose is not useful, and thus

there would be no reasonable expectation of success at the time the invention was made.

Secondary Considerations

Applicant notes again that, to applicant's knowledge, as of the priority date of the present application, no composition as recited in the amended claims had been produced or made available *despite* G.D. Searle and Co. having been selling 2.5 mg oxandrolone tablets (ANAVAR®) *since 1964*. Metcalf had been published in 1965. Yet to applicant's knowledge, no party since then has made or disclosed a solid dosage form of 10 mg oxandrolone. Applicant further notes that the Examiner has not addressed this significant secondary consideration.

Dependent claims

Applicant notes that the invention recited in each of claims 89 to 92, which claims depend from independent claim 88, is not suggested by Metcalf. A solid pharmaceutical composition comprising 10mg of oxandrolone in a unit dosage form with corn starch, hydrous lactose, hydroxypropyl methylcellulose or magnesium stearate (claims 89 to 92, respectively) is not suggested anywhere in Metcalf. Similarly, a tablet comprising 10mg of oxandrolone in a unit dosage form with corn starch, hydrous lactose, hydroxypropyl methylcellulose or magnesium stearate (claims 95 to 98, respectively) is not suggested anywhere in Metcalf. The same argument applies mutatis mutandis to new claims 102-105. Accordingly, applicants maintain that claims 89-92, 95-98 and 102-105 are not obvious over Metcalf et al. and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Request for Examiner Interview

Applicants' respectfully request an interview with the Examiner following his consideration of the present Amendment and Supplemental Information Disclosure Statement.